



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,110	12/07/2004	Javier Segado Ferran	OFIOO1.823298	1427

54042 7590 04/16/2009
WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP
250 PARK AVENUE
10TH FLOOR
NEW YORK, NY 10177

EXAMINER

AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
----------	--------------

1615

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM
ggress@wolfblock.com

Office Action Summary	Application No. 10/517,110	Applicant(s) FERRAN, JAVIER SEGADO	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment and remarks, filed on 1 January 2009.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation "crystalline form α " is deemed to be new matter. Applicants explain that page 6, lines 16-22 state that spray-dried mannitol is made up fundamentally by the crystalline form α . Examiner respectfully submits that while spray-dried mannitol may be made up of the α polymorph in-part (see SPI PHARMA technical bulletin, attached), claim 1 (as currently amended) requires that all of the mannitol be in crystalline form α . The instant specification does not state anywhere that all of the mannitol is in crystalline form α . As such, the newly added limitation is deemed to be new matter.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/12161 ("Martani").

Martani teaches a tablet which disintegrates in the oral cavity within 30 seconds (see page 9, second full-paragraph) comprising:

- at least 60% mannitol (see page 11, third full-paragraph);
- active ingredient below 10% (see example 1);
- at least 30% microcrystalline cellulose (see page 11, third full-paragraph);
- 1-15% sodium croscarmellose (see paragraph bridging pages 11 and 12);
- 0.3-5% lubricant (see page 12, first full-paragraph); and
- a density of up to 1g/ml (see page 9, second full-paragraph).

Martani does not explicitly teach the claimed particle sizes, friability values, and proportion of insoluble elements, however, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine these values through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in particle sizes, friability values, and proportion of insoluble elements will not support the patentability of subject matter encompassed

Art Unit: 1615

by the prior art unless there is evidence indicating the claimed values are critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from claimed values. Furthermore, since the prior art tablet demonstrates the same disintegration time as that being claimed, i.e. 30 seconds, and has the same ingredients (most of which are in overlapping or very close proportions), a person of ordinary skill in the art would expect that friability values, proportion of insoluble elements, and particle sizes would be similar between the prior art and the instant application.

Martani explains that the disclosed tablet is beneficial for patients who have difficulty swallowing tablets (see page 1, third full-paragraph).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a fast disintegrating tablet comprising mannitol, active agent, microcrystalline cellulose, sodium croscarmellose, and a lubricant, as taught by Martani. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a tablet because it is beneficial for patients who have difficulty swallowing tablets, as explained by Martani.

* * * * *

Response to Arguments

Applicant's arguments filed on 8 January 2009 have been fully considered but they are not persuasive.

1. Applicant argues that the prior art reference does not disclose the crystalline form α of mannitol. See remarks, page 6.

Examiner respectfully submits that this argument is moot, as the newly added limitation is deemed to be new matter (see 35 USC 112 rejection, above).

2. Applicant argues that the difference in concentration of microcrystalline cellulose between the instant claim 1 and the prior art reference is not obvious. See remarks, page 7.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP § 716.02(d) - § 716.02(e). See *In re Blondel*, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and *In re Fouche*, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was found sufficient to rebut a prima facie case of obviousness. MPEP 716.02(b). As such, examiner respectfully submits that applicant has not provided sufficient evidence of unexpected results in order to overcome the obviousness rejection.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1615

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615